

Article 4C.

Pharmacy Audit Rights.

§ 90-85.50. Declaration of pharmacy rights during audit.

- (a) The following definitions apply in this Article:
- (1) "Pharmacy" means a person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A.
 - (2) "Responsible party" means the entity responsible for payment of claims for health care services other than (i) the individual to whom the health care services were rendered or (ii) that individual's guardian or legal representative.
- (b) Notwithstanding any other provision of law, whenever a managed care company, insurance company, third-party payer, or any entity that represents a responsible party conducts an audit of the records of a pharmacy, the pharmacy has a right to all of the following:
- (1) To have at least 14 days' advance notice of the initial on-site audit for each audit cycle.
 - (2) To have any audit that involves clinical judgment be done with a pharmacist who is licensed, and is employed or working under contract with the auditing entity.
 - (3) Not to have clerical or record-keeping errors, including typographical errors, scrivener's errors, and computer errors, on a required document or record, in the absence of any other evidence, deemed fraudulent. This subdivision does not prohibit recoupment of fraudulent payments.
 - (4) If required under the terms of the contract, to have the auditing entity provide a pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media.
 - (5) To have the properly documented records of a hospital or any person authorized to prescribe controlled substances for the purpose of providing medical or pharmaceutical care for their patients transmitted by any means of communication in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug.
 - (6) To have a projection of an overpayment or underpayment based on either the number of patients served with a similar diagnosis or the number of similar prescription orders or refills for similar drugs. This subdivision does not prohibit recoupments of actual overpayments, unless the projection for overpayment or underpayment is part of a settlement by the pharmacy.
 - (7) Prior to the initiation of an audit, if the audit is conducted for an identified problem, the audit is limited to claims that are identified by prescription number.
 - (8) If an audit is conducted for a reason other than described in subdivision (6) of this subsection, the audit is limited to 100 selected prescriptions.
 - (9) If an audit reveals the necessity for a review of additional claims, to have the audit conducted on site.
 - (10) Except for audits initiated for the reason described in subdivision (6) of this subsection, to be subject to no more than one audit in one calendar year, unless fraud or misrepresentation is reasonably suspected.
 - (11) Except for cases of Food and Drug Administration regulation or drug manufacturer safety programs, to be free of recoupments based on any of the

following unless defined within the billing requirements set forth in the pharmacy provider manual not inconsistent with current North Carolina Board of Pharmacy Regulations:

- a. Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy.
 - b. A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State Board of Pharmacy.
- (12) To be subject to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim.
 - (13) Except for Medicare claims, to be subject to reversals of approval for drug, prescriber, or patient eligibility upon adjudication of a claim only in cases in which the pharmacy obtained the adjudication by fraud or misrepresentation of claim elements.
 - (14) To be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity.
 - (15) To have at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit.
 - (16) To have the period covered by an audit limited to 24 months from the date a claim was submitted to, or adjudicated by, a managed care company, an insurance company, a third-party payer, or any entity that represents responsible parties, unless a longer period is permitted by a federal plan under federal law.
 - (17) Not to be subject to the initiation or scheduling of audits during the first five calendar days of any month due to the high volume of prescriptions filled during that time, without the express consent of the pharmacy. The pharmacy shall cooperate with the auditor to establish an alternate date should the audit fall within the days excluded.
 - (18) To have the preliminary audit report delivered to the pharmacy within 120 days after conclusion of the audit.
 - (19) To have a final audit report delivered to the pharmacy within 90 days after the end of the appeals period, as provided for in G.S. 90-85.51.
 - (20) Not to have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans.
 - (21) Not to be subject to recoupment on any portion of the reimbursement for the dispensed product of a prescription, unless otherwise provided in this subdivision:
 - a. Recoupment of reimbursement, or a portion of reimbursement, for the dispensed product of a prescription may be had in the following cases:
 1. Fraud or other intentional and willful misrepresentation evidenced by a review of the claims data, statements, physical review, or other investigative methods.
 2. Dispensing in excess of the benefit design, as established by the plan sponsor.

3. Prescriptions not filled in accordance with the prescriber's order.
 4. Actual overpayment to the pharmacy.
- b. Recoupment of claims in cases set out in sub-subdivision a. of this subdivision shall be based on the actual financial harm to the entity or the actual underpayment or overpayment. Calculations of overpayments shall not include dispensing fees unless one of the following conditions is present:
1. A prescription was not actually dispensed.
 2. The prescriber denied authorization.
 3. The prescription dispensed was a medication error by the pharmacy. For purposes of this subdivision, a medication error is a dispensing of the wrong drug or dispensing to the wrong patient or dispensing with the wrong directions.
 4. The identified overpayment is based solely on an extra dispensing fee.
 5. The pharmacy was noncompliant with Risk Evaluation and Mitigation Strategies (REMS) program guidelines.
 6. There was insufficient documentation, including electronically stored information, as described in this subsection.
 7. Fraud or other intentional and willful misrepresentation by the pharmacy.
- (22) To have an audit based only on information obtained by the entity conducting the audit and not based on any audit report or other information gained from an audit conducted by a different auditing entity. This subdivision does not prohibit an auditing entity from using an earlier audit report prepared by that auditing entity for the same pharmacy. Except as required by State or federal law, an entity conducting an audit may have access to a pharmacy's previous audit report only if the previous report was prepared by that entity.
- (23) If the audit is conducted by a vendor or subcontractor, that entity is required to identify the responsible party on whose behalf the audit is being conducted without having this information being requested.
- (24) To use any prescription that complies with federal or State laws and regulations at the time of dispensing to validate a claim in connection with a prescription, prescription refill, or a change in a prescription. (2011-375, s. 1; 2013-379, s. 3.)

§ 90-85.51. Mandatory appeals process.

(a) Each entity that conducts an audit of a pharmacy shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(b) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings.

(c) Each entity conducting an audit shall provide a copy, if required under contractual terms, of the audit findings to the plan sponsor after completion of any appeals process. (2011-375, s. 1.)

§ 90-85.52. Pharmacy audit recoupments.

(a) The entity conducting an audit shall not recoup any disputed funds, charges, or other penalties from a pharmacy until (i) the deadline for initiating the appeals process established pursuant to G.S. 90-85.51 has elapsed or (ii) after the final internal disposition of an audit, including the appeals process as set forth in G.S. 90-85.51, whichever is later, unless fraud or misrepresentation is reasonably suspected.

(b) Recoupment on an audit shall be refunded to the responsible party as contractually agreed upon by the parties.

(c) The entity conducting the audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The responsible party and the entity conducting the audit have entered into a contract that explicitly states the percentage charge or assessment to the responsible party.

(2) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped. (2011-375, s. 1; 2013-379, s. 4.)

§ 90-85.53. Applicability.

This Article does not apply to any audit, review, or investigation that involves alleged Medicaid fraud, Medicaid abuse, insurance fraud, or other criminal fraud or misrepresentation. (2011-375, s. 1.)